

Amendment

U.S. Patent Application Serial No. 10/723,692

Office Action Dated: September 3, 2009

Inventor: James B. McCormick

Attorney Docket No. 46521-56177

REMARKS

This Amendment is filed in response to the Office Action dated September 3, 2009.

Rejection Under 35 U.S.C. § 102(b):

Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Levine et al. (U.S. Patent No. 4,420,353). Claim 1 is now amended to recite: "...a histological examination liquid permeable target disposed on the foldable liquid permeable sheet within the edges of said sheet, sheet and attached with a **glue spot**,...." (emphasis added). Support for this amendment can be found in Applicant's Published Patent Application No. 2005/0112032 in Paragraph [0024], Lines 3-12, which recites: "Target 14 may be loosely placed on or tacked to sheet 12. If target 14 is tacked to sheet 12, it may be fixed by a **glue spot**, but target 14 must be mechanically separable from sheet 12 through light pulling pressure with forceps that grasp target 14 after processing. Generally, any adhesive may be used for the glue spot as long as the adhesive is not soluble in the processing fluids typically used in histological sample preparation. For example, a hot melt polyolefin adhesive may be used for the glue spot." (emphasis added). No new matter has been added. Moreover, there is now a **histological examination liquid permeable sheet** and a **histological examination liquid permeable target** recited in Claim 1. Support for this amendment can be found

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in Applicant's Published Patent Application No. 2005/0112032 in Paragraph [0024], Lines 8-10, which recites: "Generally, any adhesive may be used for the glue spot as long as the adhesive is not soluble in the processing fluids typically used in histological sample preparation." (emphasis added). Therefore, no new matter has been added.

Under 35 U.S.C. §102, "the identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Moreover, when evaluating a claim for anticipation, all claim limitations must be considered. *In re Evanega*, 829 F.2d 1110, 4 U.S.P.Q.2d 1249 (Fed. Cir. 1987). In this case, the foldable histological examination liquid permeable sheet and the histological examination liquid permeable target are cited by the Examiner in the Office Action on Page 2, Lines 20-21 as being the same, single, solitary sheet 8 in Levine. It is respectfully believed to be axiomatic when two separate and detachable items are recited in a patent claim, the presence of a single, solitary item in a prior art reference does not suffice as a proper rejection under 35 U.S.C. Section 102(b). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added).

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Moreover, a glue gel on the absorbent layer in Levine would be problematic and could prevent the stool sample from reacting with the reagent or create an unwanted chemical reaction with the applied reagent that would destroy Levine for its intended purpose.

In addition, the stool sample of Levine is a **laminated structure** intended for receiving a reagent and Levine's **impermeable composite** clearly does not explicitly or inherently disclose "...a foldable **histological examination liquid permeable sheet** having edges; a **histological examination liquid permeable target** disposed on the foldable histological examination liquid permeable sheet within the edges of said sheet, sheet and attached with a glue spot, a **foldable histological examination liquid permeable sheet that allows the passage of liquid therethrough.**" (Applicant's Claim 1) (emphasis added).

The type of testing using liquids in Levine is described as: "Preferably, the impermeable layer 12 will be made of transparent plastic material so that, once the necessary reagents are applied to the stool spots S, the pouch may be reclosed and the presence or absence of the characteristic blue color may be observed through the impermeable layer 12." (emphasis added) (Levine, Column 4, Lines 40-45). Therefore, the use of a passing liquid, e.g., reagent, is performed with an impermeable layer, which directly contradicts Applicant's Claim 1, which recites "a foldable **histological examination liquid permeable sheet.**" (emphasis added).

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In addition, a person is forced to remove the additional layers of the "laminate", i.e., layers 4 and 12, to get to the absorbent layer 8. There is no disclosure of an overlapping structure in Levine except that which specifically includes impermeable layers. These impermeable layers will prevent the passage of fluids therethrough. When evaluating a claim for anticipation, all claim limitations must be considered. *In re Evanega*, 829 F.2d 1110, 4 U.S.P.Q.2d 1249 (Fed. Cir. 1987). Moreover, the fact that layers would need to be removed directly counters that the device, **in its normal and usual operation**, will inherently perform the claimed process and anticipate the Applicant's Invention when the other layers must be removed and the specimen is not directly placed directly on absorbent material 8 in the normal course of operation.

Moreover, Claim 1 requires: "...a histological examination liquid permeable target disposed on the foldable liquid permeable sheet within the edges of said foldable histological examination liquid sheet, and attached with a glue spot." In marked contrast, the stool sample in Levine is **placed on the screening layer 4** and with some of the stool sample passing through the holes in the screening layer 4. For a valid rejection under 35 U.S.C. §102, "all words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

Therefore, it is respectfully believed that Claim 1 overcomes the rejection under 35 U.S.C. § 102(b) and is patentable over Levine and is in condition for allowance.

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Claim 2 was rejected under 35 U.S.C. § 102(b) as being anticipated by Levine et al. (U.S. Patent No. 4,420,353). Claim 2 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 102(b) rejection over Levine in the same manner as Claim 1 as described above. If an independent claim is not anticipated, then any claim depending therefrom is also not anticipated. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

In addition, Claim 2 is amended to recite: “wherein the malleable material securing strip is attached at an edge of the histological examination liquid permeable sheet to allow for closure and clamping of the folded flap portions as well as positive release of the folded flap portions.” Support for this amendment can be found on Pages 2 and 3, Paragraph [0028], Lines 1-7 of Applicant’s Published Patent Application No. 2005/0112032 as follows: “Malleable securing strip 18 can be any material that is formable or malleable, but it is preferred that strip 18 is either a metal wire or a strip of heavy metal foil. The wire or foil needs to have appropriate dimensions to allow for a one time use-easy closure and clamping, as well as, positive release of extended flap portions 16a-d (described in more detail below).” Therefore, no new matter has been added. In marked contrast, the adhesive strips 22 recited in Levine: “As noted in FIG. 4, after the device is used, the releasable adhesive strips 22 allow the screening layer 4 to be peeled off of the laminate, as indicated by 4’, and discarded in the toilet by the user. It will be appreciated that the screening layer 4 acts, by means of the openings

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20, to control the amount of stool which is deposited on the absorbent layer 8.”
(emphasis added) (Levine, Column 3, Lines 62-68). Therefore, the adhesive strips 22 are completely blocked by the screening layer 4 and would need to be removed. Moreover, layer 8 is **laminated to an impermeable layer 12 as shown in FIG. 1 with the resulting combination being an impermeable structure.**

Therefore, it is respectfully believed that Claim 2 overcomes the rejection under 35 U.S.C. § 102(b) and is patentable over Levine and is in condition for allowance.

Claim 7 was rejected under 35 U.S.C. § 102(b) as being anticipated by Levine et al. (U.S. Patent No. 4,420,353). Claim 7 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 102(b) rejection over Levine in the same manner as Claim 1 as described above. If an independent claim is not anticipated, then any claim depending therefrom is also not anticipated. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

Moreover, Applicant's Claim 7 requires: “...an X and Y coordinate marking lines **centered** on the histological examination liquid permeable target.” Page 2, Paragraph [0025], Lines 1-3 of Applicant's Published Patent Application No. 2005/0112032 as follows: “Fourth, permeable target 14 may also contain a printed X/Y coordinate marking system 20 **centered** on target 14 as shown in FIG. 1.” (emphasis added). Therefore, no new matter has been added. The alleged X and Y marking lines in Levine, Y lines are formed from folds 28 and 30 and adhesive strips forming the X

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lines. However, these lines are clearly not centered. Once again, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

Therefore, it is respectfully believed that Claim 7 overcomes the rejection under 35 U.S.C. § 102(b) and is patentable over Levine and is in condition for allowance.

Rejection Under 35 U.S.C. § 103 (a):

Claim 3 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Levine et al. (U.S. Patent No. 4,420,353) in view of Rochette (U.S. Patent No. 3,537,636). Claim 3 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 103(a) rejection over Levine in the same manner as Claim 1 as described above. If an independent claim is not obvious or anticipated, then any claim depending therefrom is also not obvious or anticipated. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

Claim 3 requires that the malleable securing strip is a **metal wire**. This does not mean the malleable securing strip includes or comprises a metal wire **but the malleable securing strip is a metal wire**.

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The adhesive strips 22, alleged to be the malleable securing strip, disclosed in Levine used for: "As noted in FIG. 4, after the device is used, the releasable adhesive strips 22 allow the screening layer 4 to be peeled off of the laminate, as indicated by 4', and discarded in the toilet by the user." (emphasis added) (Levine, Column 3, Lines 62-65). Therefore, the adhesive strips play an instrumental role in Levine and this function of being able to remove the screening layer 4 from the laminate would be absolutely destroyed by this substitution of a metal wire for adhesive strips. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). Moreover, "all words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970).

"To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference; (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination,

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each element merely would have performed the same function as it did separately.”
(emphasis added). Federal Register / Volume 72, No. 195 / Wednesday, October 10, 2007 / Notices, Page 57529, “Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.” It is respectfully believed that it is very clear that this rejection completely fails the new KSR Guidelines promulgated by the United States Patent Office since a metal wire would not operate like adhesive strips 22 to retain the screening layer 4 and allow the screening layer 4 to be able to be peeled off and removed. A person of ordinary skill in the art would not make a substitution of the wire disclosed in Rochette for the adhesive strips 22 disclosed in Levine if this substitution would destroy the function and purpose of the stool sampling device disclosed in Levine.

Therefore, it is respectfully believed that Claim 3 overcomes the rejection under 35 U.S.C. § 103(a) and is patentable over Levine in view of Rochette and is in condition for allowance.

Claim 4 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Levine et al. (U.S. Patent No. 4,420,353) in view of Rochette (U.S. Patent No. 3,537,636). Claim 4 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 103(a) rejection over Levine in the same manner as Claim 1 as described above. If an independent claim is not obvious or anticipated, then any

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claim depending therefrom is also not obvious or anticipated. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

Claim 4 requires that the malleable securing strip is **metal foil**. This does not mean the malleable securing strip includes or comprises metal foil but the malleable securing strip is metal foil.

The adhesive strips 22, alleged to be the malleable securing strip, disclosed in Levine used for: "As noted in FIG. 4, after the device is used, the releasable adhesive strips 22 allow the screening layer 4 to be peeled off of the laminate, as indicated by 4', and discarded in the toilet by the user." (emphasis added) (Levine, Column 3, Lines 62-65). Therefore, the adhesive strips play an instrumental role in Levine and this function of being able to remove the screening layer 4 from the laminate would be absolutely destroyed by this substitution. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). Moreover, "all words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970).

"To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a **finding that the prior art included each element claimed, although**

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not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference; **(2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately.**" (emphasis added). Federal Register / Volume 72, No. 195 / Wednesday, October 10, 2007 / Notices, Page 57529, "Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc." It is respectfully believed that it is very clear that this rejection completely fails the new KSR Guidelines promulgated by the United States Patent Office since metal foil would not operate like adhesive strips 22 to retain the screening layer 4 and allow the screening layer 4 to be able to be peeled off and removed. A person of ordinary skill in the art would not make a substitution of the metal foil for the adhesive strips 22 disclosed in Levine if this substitution would destroy the function and purpose of the stool sampling device disclosed in Levine.

Moreover, metal foil is not disclosed in either Levine or Rochette. It is respectfully believed to be axiomatic that something that is not disclosed in either of two cited references cannot come into being by their combination. Consequently, "all words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A.

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1970]. It is well established in U.S. Patent Law as well as the Manual for Patent Examining Procedure (M.P.E.P.) § 2143.03 that "to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974) (emphasis added).

Therefore, it is respectfully believed that Claim 4 overcomes the rejection under 35 U.S.C. § 103(a) and is patentable over Levine in view of Rochette and is in condition for allowance.

Claim 5 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Levine et al. (U.S. Patent No. 4,420,353) in view of Williamson (U.S. Patent No. 5,817,032). Claim 5 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 103(a) rejection over Levine in the same manner as Claim 1 as described above. If an independent claim is not obvious or anticipated, then any claim depending therefrom is also not obvious or anticipated. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

The target in Levine is a stool sample. The addition of a reagent to the stool sample makes sense because there is a chemical reaction with the stool sample to determine the presence of occult blood. Therefore, the complete access to the stool sample is required so that a chemical reaction can take place. In marked contrast, the Examiner is alleging on Page 4, Lines 11-21 of the September 3, 2009 Office Action that: "Williamson discloses in his abstract placing a tissue biopsy sample on a tissue

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trapping and supporting material that can withstand tissue preparation procedures and which can be cut with a mictotome. Williamson further discloses spraying a **thin layer of agar or other gel over the tissue** and filter (i.e., col. 16, lines 43-59). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Levine's liquid permeable target by adding a **binder, such as agar, to the tissue sample** because adding agar to tissue samples is well known as "cell block preparation," which is a technique that allows the user to easily prepare the sample for analysis (i.e., Williamson, col. 1, lines 32-37)." (emphasis added). Therefore, adding a binder and using a tissue trapping material would operate to destroy the invention disclosed in Levine and prevent an even and consistent chemical reaction between the stool sample and the reagent from taking place. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959).

"To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a

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single prior art reference; (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately.” (emphasis added). Federal Register / Volume 72, No. 195 / Wednesday, October 10, 2007 / Notices, Page 57529, “Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.” It is respectfully believed that it is very clear that this rejection completely fails the new KSR Guidelines promulgated by the United States Patent Office since adding a binder or gel would most likely operate to prevent or inhibit a reaction between a stool sample and reagent from taking place. It would not be the same function as performed separately and no one with ordinary skill in the art would add material that would prevent or inhibit the reaction between the stool sample and the reagent from taking place since that is the purpose and function of Levine.

Therefore, it is respectfully believed that Claim 5 overcomes the rejection under 35 U.S.C. § 103(a) and is patentable over Levine in view of Williamson and is in condition for allowance.

Claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Levine et al. (U.S. Patent No. 4,420,353). Claim 6 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 103(a) rejection over Levine in the same manner as Claim 1 as described above. If an independent claim is not

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obvious or anticipated, then any claim depending therefrom is also not obvious or anticipated. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

Claim 6 is now amended to recite: "...**having a glue spot located thereon for attaching the histological examination liquid permeable target to the foldable histological examination liquid permeable sheet....**" (emphasis added). Support for this amendment can be found in Applicant's Published Patent Application No. 2005/0112032 in Paragraph [0024], Lines 3-12, which recites: "Target 14 may be loosely placed on or tacked to sheet 12.

If target 14 is tacked to sheet 12, it may be fixed by a glue spot, but target 14 must be mechanically separable from sheet 12 through light pulling pressure with forceps that grasp target 14 after processing. Generally, any adhesive may be used for the glue spot as long as the adhesive is not soluble in the processing fluids typically used in histological sample preparation. For example, a hot melt polyolefin adhesive may be used for the glue spot." (emphasis added). No new matter has been added.

"To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference; (2) a finding that one of ordinary skill in the

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art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately." (emphasis added). Federal Register / Volume 72, No. 195 / Wednesday, October 10, 2007 / Notices, Page 57529, "Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc." It is respectfully believed that it is very clear that this rejection completely fails the new KSR Guidelines promulgated by the United States Patent Office since a glue spot to secure the histological examination liquid permeable target to the foldable histological examination liquid permeable sheet is wholly absent from Levine. Most importantly, the foldable histological examination liquid permeable sheet and the histological examination liquid permeable target are cited by the Examiner in the Office Action on Page 2, Lines 20-21 as being the same, single sheet 8 in Levine. It is respectfully believed to be axiomatic when two separate and detachable items are recited in a patent claim, the presence of a single, solitary item in a prior art reference does not suffice as a proper rejection under 35 U.S.C. Section 103(a) since the requirement under the Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc. of: "the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference" is simply not available with a single sheet 8 in

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Levine functioning as both the histological examination liquid permeable target and the foldable histological examination liquid permeable sheet **and there is no glue spot connecting the two items located in between.** "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

Therefore, it is respectfully believed that Claim 6 overcomes the rejection under 35 U.S.C. § 103 (a) and is patentable over Levine and is in condition for allowance.

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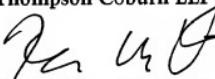
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Therefore, it is now believed that all of the pending Claims, i.e., Claims 1-7, in the present application are in condition for allowance. Favorable action and allowance of the Claims is therefore respectfully requested. If any issue regarding allowability of any of the pending Claims in the present application could be readily resolved, or if other action could be taken to further advance this application such as an Examiner's Amendment, or if the Examiner should have any questions regarding the present Amendment, it is respectfully requested that the Examiner please telephone the Applicant's undersigned attorney in this regard.

Respectfully submitted,

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